
Press Release

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Japan first country to approve VAL001 patent

Japan has as the first country in the world approved Respiratorius patent application VAL001, "A Pharmaceutical Composition Comprising a HDAC inhibitor and a Steroid and the Use thereof."

The patent gives Respiratorius market exclusivity in Japan for a combination of HDAC inhibitors and steroid pre-treatment before chemotherapy (R-CHOP) in the treatment of diffuse large B-cell lymphoma (DLBCL), a lymphoma that annually affects about 60,000 people in the US and Europe. DLBCL is the most common type of Non-Hodgkin's lymphoma, which comprises 30% of the affected patients in the EU and the US, while in Japan the proportion is significantly higher, 45%.

A clinical Phase I/IIa study of VAL001 is currently running at the Skåne Oncology Clinic, SUS Lund / Malmö, Oncology Clinic at Uppsala University Hospital, and the Cancer Centre, University Hospital in Umeå. In the study, VAL001 is given as pre-treatment prior to standard chemotherapy including rituximab (R-CHOP), in the treatment of diffuse large B-cell lymphoma.

An interim analysis of the Phase I/IIa study results were presented at the end of April 2016. The analysis regards the overall survival of patients treated with VAL001 and R-CHOP, and revealed that 1-year survival rate was 100% and the 2- year survival rate was 95%. For comparison, a matched reference population of 843 patients from the Swedish registry of lymphoma patients treated with R-CHOP alone, showed a 1-year survival of 90% and 2-year survival of 82%. The interim analysis of the VAL001 study outcome was significantly better than those of the reference material for both the 1-year survival (95% significance) and 2-year survival (90% significance).

"The approval of the patent application for VAL001 is of significant importance for the company. Japan is a potentially important market for VAL001 and the approval strengthens our market position", says CEO Johan Drott in a statement.

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Respiratorius AB (publ) is developing drug candidates with the goal to launch drugs for common diseases like cancer, chronic obstructive pulmonary disease (COPD) and severe asthma. In addition, the company portfolio also holds a project for improved diagnosis of certain cardiovascular diseases.